



Increasing Need for Chemical Measurements of Known Quality



Presented to PITTCON 2003 Workshop:
Providing Measurements of Known Quality:
How Do We Get There?

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Presentation Overview

- Components of Quality Measurements
- Mechanisms for Evaluating Laboratory Quality
- International Recognition System
- Questions

Components of Quality Measurements

Evaluation of Uncertainty

Traceability

Validated Test Methods

Competent Personnel

Quality System

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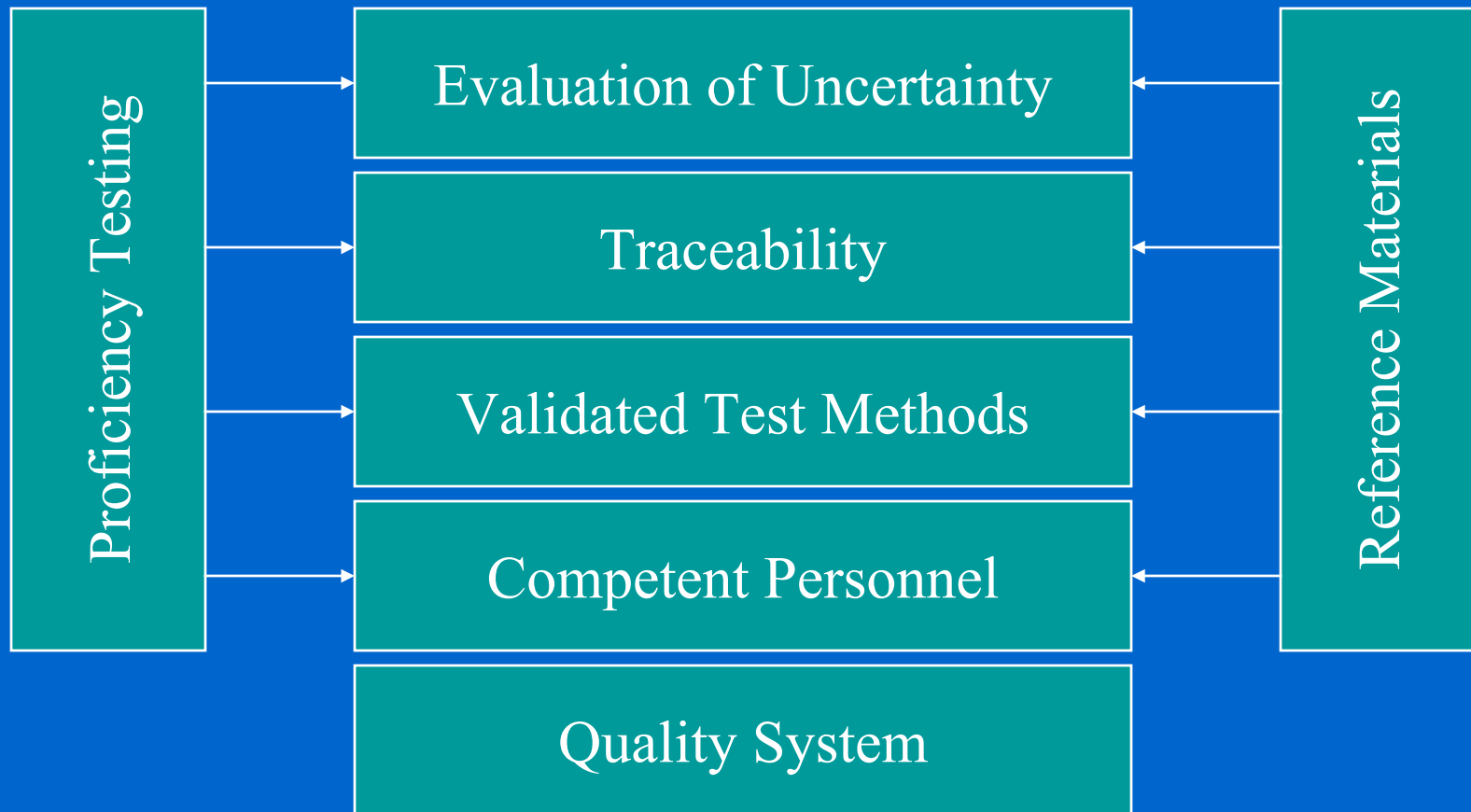
Components of Quality Measurements

Quality System

Quality System Elements

- Quality Policy Quality System
- Documented procedures
- Processes for self-assessment
- Corrective and preventive action processes
- Complaint handling
- Document control
- Records
- Continuous improvement

Components of Quality Measurements



Quality vs. Risk

- Investment in assuring quality dependent on importance of results
- Conformity assessment - any activity concerned with determining directly or indirectly that relevant requirements are fulfilled (ISO/IEC Guide 2:1996)
- Transparency, confidence increase with level of conformity assessment

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Mechanisms for Evaluating Laboratory Quality



Depth of Assessment

- Accreditation
- Certification
(a.k.a. Registration)
- Self declaration



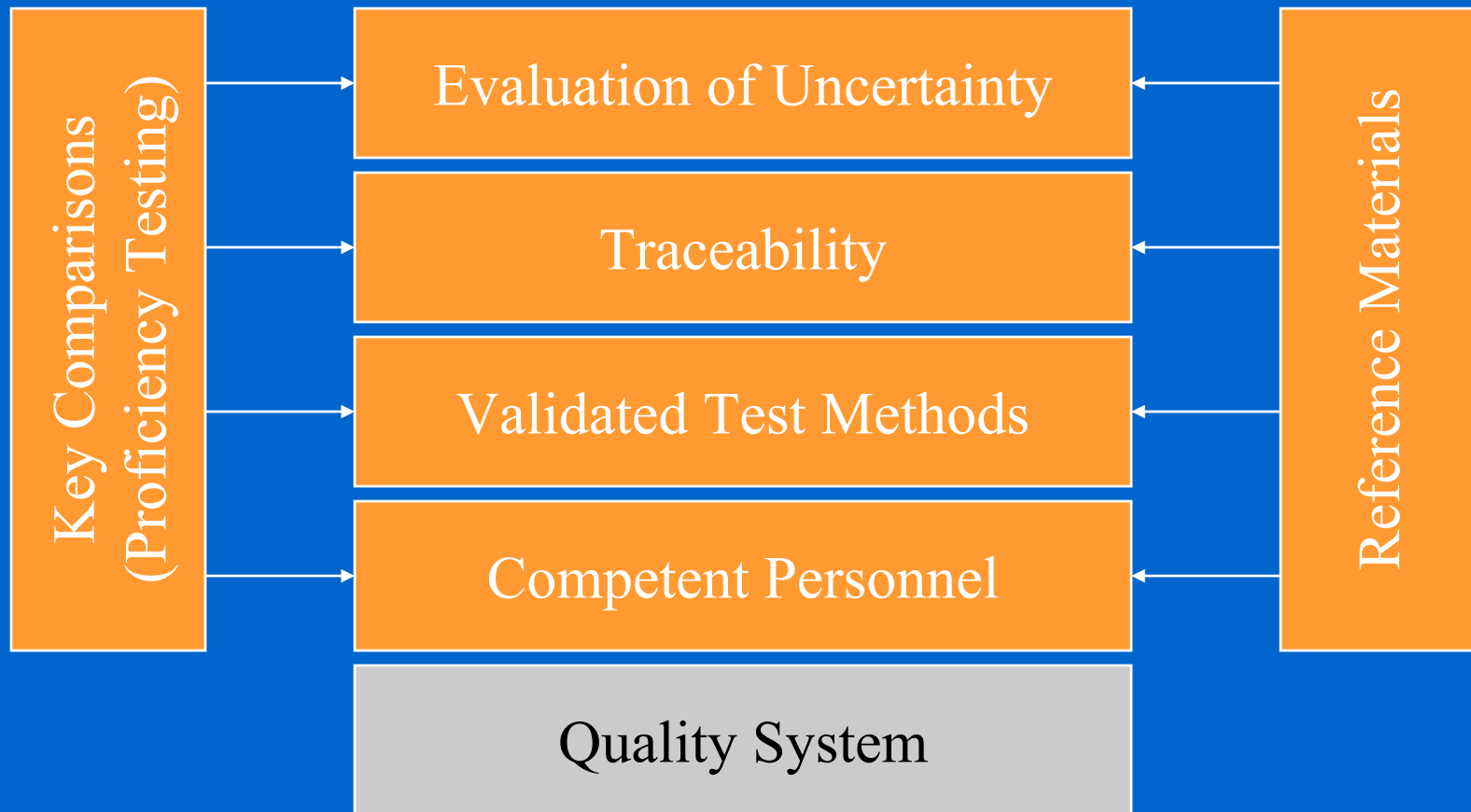
Transparency

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Self Declaration

- Supplier (1st party) gives written assurance that its product meets specified requirements
- Acceptability dependent upon:
 - Potential use of data
 - Confidence in likelihood of compliance

Common Example of Self Declaration - NMIs



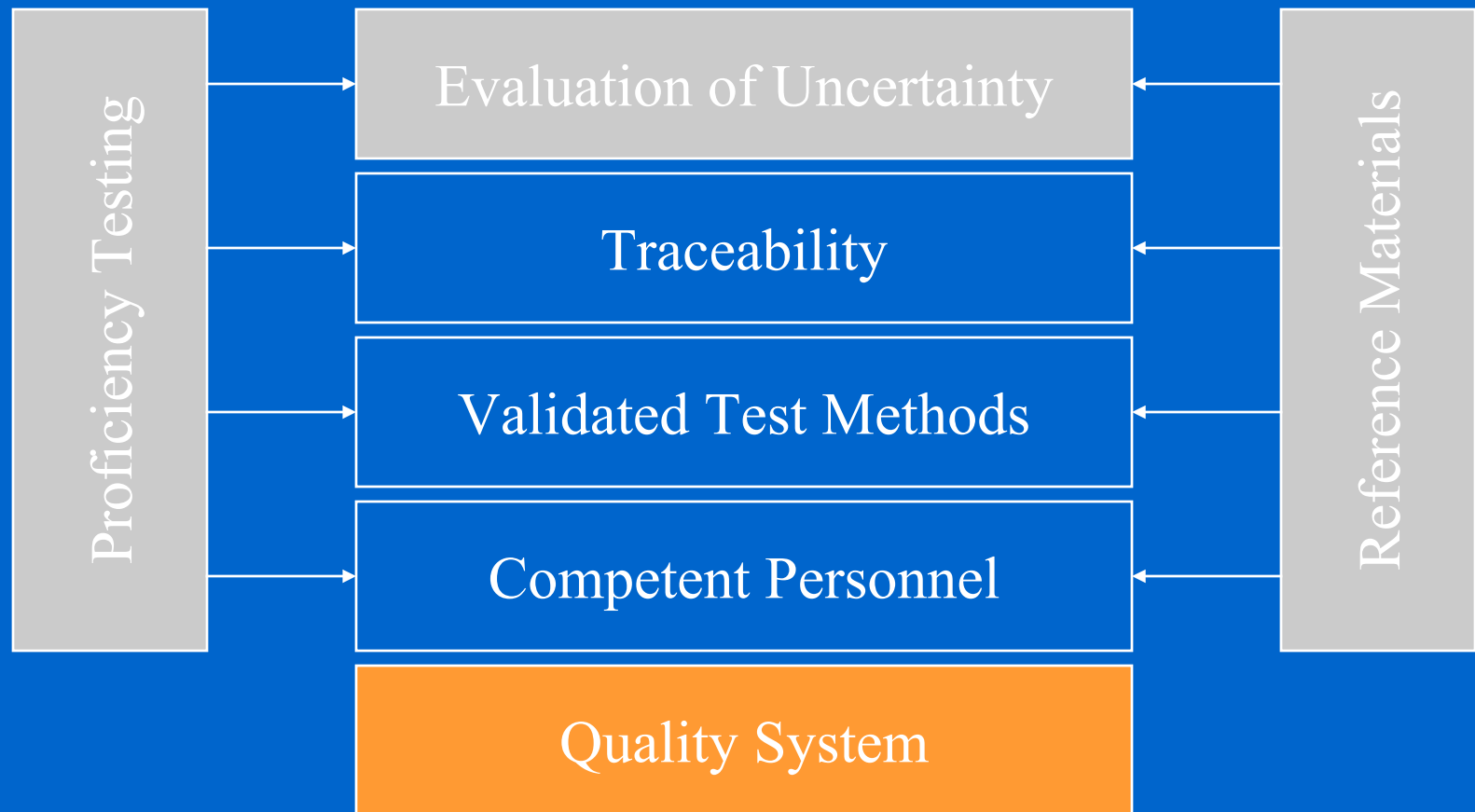
Certification

- Third party gives written assurance that a product, process, or service conforms to specified requirements
- Examples:
 - Product certification (ISO Guide 65)
 - Environmental management system registration (ISO 14000)
 - Quality management system registration (ISO 9001)
 - ~~– Certification of laboratories to ISO/IEC 17025~~

Certification of Laboratories to ISO 9001

- More transparent than self-certification
- Generic requirements, can be applied (or misapplied) to laboratories
- Emphasis is on compliance with quality management system requirements
- Auditors have detailed experience in management systems

Certification to ISO 9001



Accreditation

- Third party assessment of competence
- Laboratory accreditation
 - ABs operate against ISO/IEC Guide 58
 - Assess labs against ISO/IEC 17025 and specific technical requirements
- Assessors are technical experts in testing
- Accreditation granted for specific tests
- Greater transparency

Laboratory Accreditation - ISO/IEC 17025



Laboratory Accreditation - ISO/IEC 17025

- What it does:
 - Assure laboratory meets quality management system requirements (ISO 9001:1994)
 - Provide assurance that laboratory has demonstrated a known level of competence
 - Provide a specific list of competencies
- What it does not do:
 - Guarantee valid of test results

Which Is Appropriate?

- IAF-ILAC-ISO/CASCO Joint Working Group on Image and Integrity of Conformity Assessment Communiqué
- For laboratory, depends primarily on needs of customers
- For laboratory users, depends on desired level of assessment and confidence
 - Reassurance of specific technical competence
 - Compliance with management system only

Who Accredits the Accreditors?

- Peer review process
 - Evaluate headquarters operations
 - Witness assessments
 - Some groups include stakeholders in process
- Done at national, regional, and global levels
- Results in mutual recognition of accreditations

Laboratory Accreditation Recognition - National

- NACLA - National Cooperation for Laboratory Accreditation
 - Signed MOU with NIST to coordinate recognition of US laboratory ABs
- NELAC - National Environmental Laboratory Accreditation Cooperation
 - Association of state agencies
 - Reciprocity of accreditation among participating states

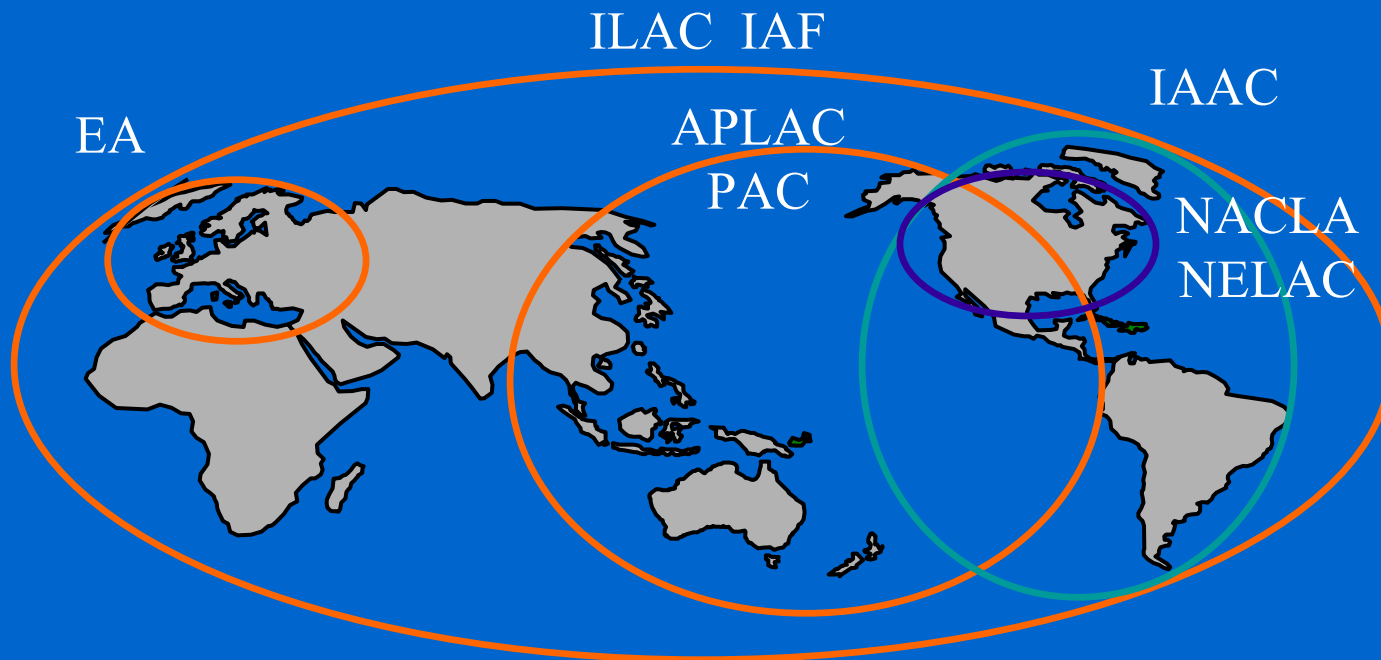
• • • Accreditation Recognition - Regional Bodies

- APLAC - Asia Pacific Laboratory Accreditation Cooperation
 - Laboratory
- EA - European cooperation for Accreditation
 - Laboratory & Certification
- IAAC - Inter-American Accreditation Cooperation
 - Laboratory & Certification
- PAC - Pacific Accreditation Cooperation
 - Certification

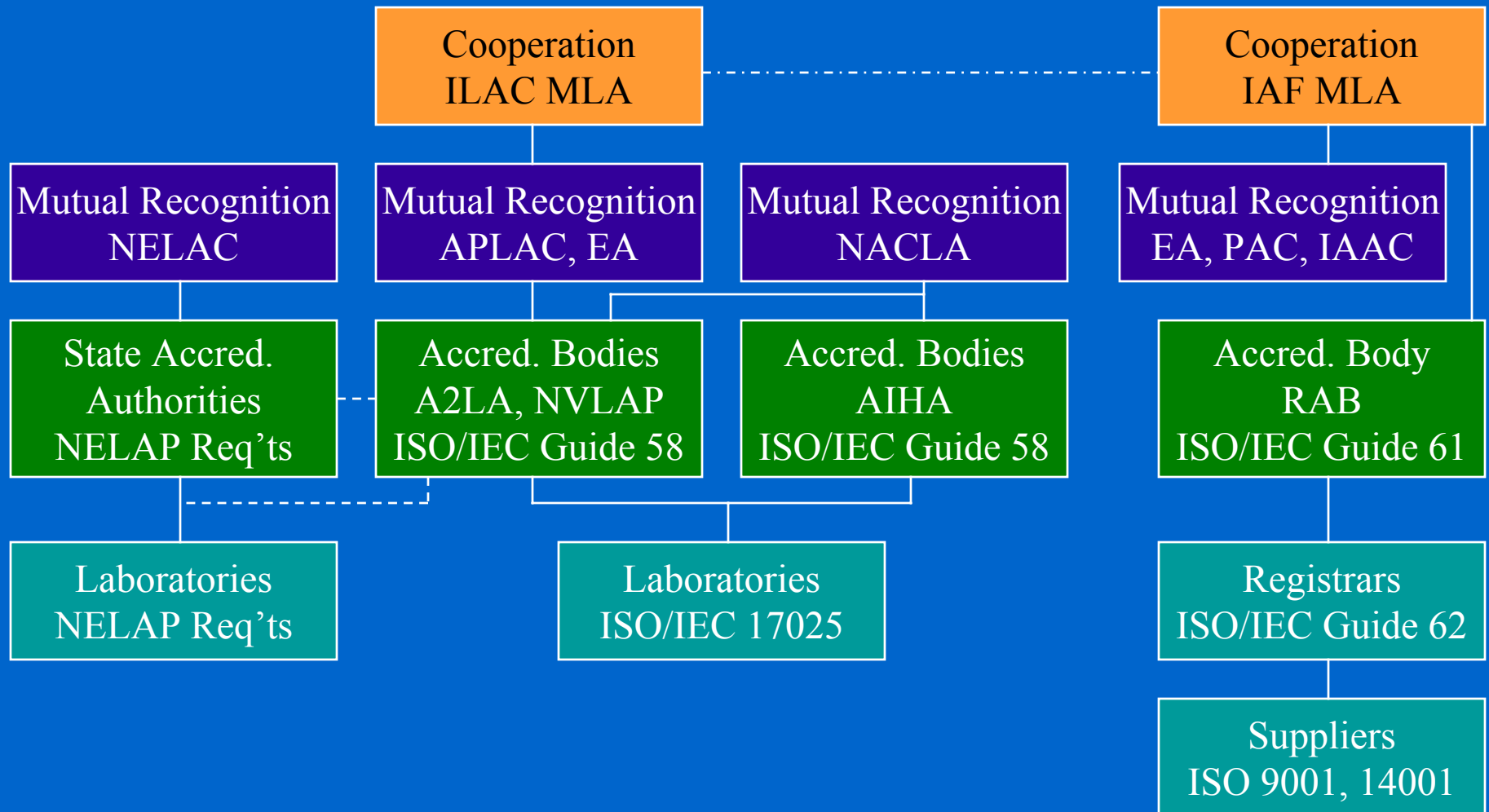
Global Recognition Arrangements

- ILAC - International Laboratory Accreditation Cooperation
- IAF - International Accreditation Forum
- Normally supported by regional bodies
- Possible to go directly to global body for recognition

International Mutual Recognition



US Conformity Assessment Hierarchy



Benefits of International Conformity Assessment System

- Provides:
 - International comparability in assessment of competence
 - Validation of assessment methods
- Facilitates trade
 - Regulators, industry rely on accreditation
 - Reduces or eliminates need for re-testing when products cross borders

Current Events

- ISO/IEC 17025 being realigned to address disconnect between Section 4 (based on ISO 9001:1994) and ISO 9001:2000
- Working group developing an amendment:
 - Labs meeting ISO/IEC 17025 also meet *principles* of ISO 9001:2000
 - Statement that 17025 not for certification
 - Editorial changes to Section 4
 - Not expected to significantly affect laboratories

Conclusions...

- Various systems in place for independent evaluation of laboratory quality
- Laboratories, users have options depending on intended use of data
- Provides a basis for comparison
- Still distinction in levels of competence above basic requirements
- True quality depends on laboratory implementation and commitment

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